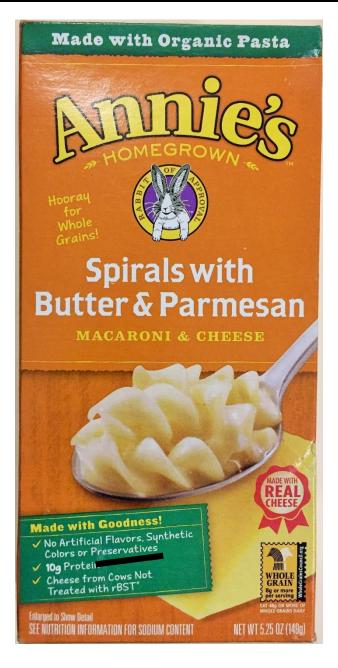
Exhibit A

Spirals with Butter & Parmesan Macaroni & Cheese

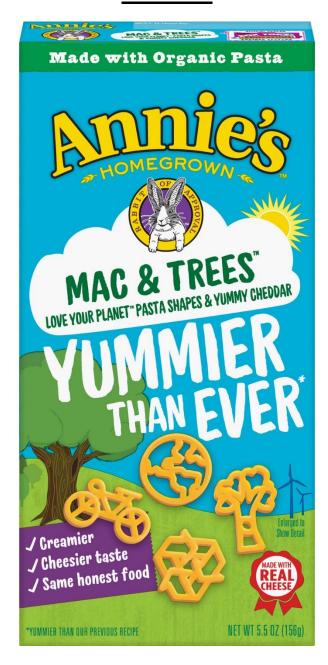


BEST INGREDIENTS:
ORGANIC PASTA (ORGANIC WHEAT
FLOUR, ORGANIC WHOLE GRAIN
WHEAT FLOUR), CHEESE BLEND
(WHEY, PARMESAN CHEESE
[CULTURED PART-SKIM MILK,
SALT, NON-ANIMAL ENZYMES],
BUTTER, NONFAT MILK, SALT,
CORN STARCH, NATURAL FLAVOR,
SODIUM PHOSPHATE, LACTIC
ACID, CITRIC ACID, SILICON
DIOXIDE [FOR ANTICAKING]).

CONTAINS WHEAT AND MILK INGREDIENTS.

MANUFACTURED FOR ANNIE'S, INC. 1610 5TH ST., BERKELEY, CA 94710

Mac and Trees Yummier Than Ever



MEET BERNIE!

Bernie was Annie's pet Dutch rabbit. When she started the company, Annie chose him to be our official "rabbit of approval" representing the simplicity, care and goodness in all of our products



In celebration of nearly 30 years of mac & cheese goodness, we've gone all out to make it better. In that spirit, our mac & cheese masters headed back to the kitchen on a mission for more yum. After hundreds of batches and licked bowls, we came up with a richer, more flavorful recipe. Even the noodle got an upgrade for better texture! You'll notice, however, that one thing is staying the same - our commitment to never using any GMOs, artificial flavors, synthetic colors or preservatives Aside from this delicious mac & cheese, one of the things that brings us the most joy is giving back to help schools create and maintain vibrant school gardens. Since 2008, our support has helped connect more than 1 million kids across America to real food. Good growing! SCHOOL

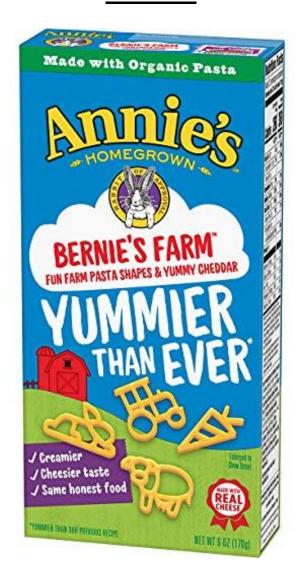
Bye for now,

All of us at Annie's

BEST INGREDIENTS: ORGANIC PASTA (ORGANIC WHEAT FLOUR, ORGANIC WHOLE GRAIN WHEAT FLOUR), WHEY, CULTURED CREAM, NONFAT MILK, SALT, BUTTER (PASTEURIZED CREAM, SALT), DRIED **CHEDDAR CHEESE** (CULTURED PASTEURIZED MILK, SALT, NON-ANIMAL ENZYMES), **CORN STARCH**, **CITRIC ACID**. ANNATTO EXTRACT (FOR COLOR), LACTIC ACID, SUNFLOWER LECITHIN, SILICON **DIOXIDE (FOR ANTICAKING), SODIUM** PHOSPHATE.

CONTAINS WHEAT AND MILK INGREDIENTS.

Bernie's Farm Yummier Than Ever



MEET BERNIE!

Bernie was Annie's pet Dutch rubbit. When she started the company, Annie chose him to be our official "rabbit of approval" representing the simplicity, care and goodness in all of our products



Dear Friend,

In celebration of nearly 30 years of mac & cheese goodness, we've gone all out to make it better. In that spirit, our mac & cheese masters headed back to the kitchen on a mission for more yum. After hundreds of batches and licked bowls, we came up with a richer, more flavorful recipe. Even the noodle got an upgrade for better texture! You'll notice, however, that one thing is staying the same - our commitment to never using any GMOs, artificial flavors, synthetic colors or preservatives.

We get letters every day from parents and kids who love our honest foods. We even have a bulletin board where we post our favorites! When our team discovered a way to make our recipe even more totally delicious, we had you and your letters in mind. So make a bowl and tell us what you think!

Bue for now,

All of us at Annie's



Annie's Way In 12 Minutes



EXTEA O ADD:

TASTY! 3 This reduced

fat milk and

butter to the warm saucepan.

2 Tosp unsafed

O BOIL: 6 cups water in a medium saucepen.



O STIR IN: pasta, bring to boil. Cook 10-12 minutes, or until done, stirring occasionally.



O DRAIN PASTA: in colander. While pasta is draining...



ANNIE'S SUGGESTIONS:

For an even RICHER flavor, add an additional 2 tablespoons unsafted butter. For a CREAMY, TANGY version, replace milk with 3 tablespoons of plain whole milk yogurt.

BEST INGREDIENTS: ORGANIC PASTA
(ORGANIC WHEAT FLOUR, ORGANIC
WHOLE GRAIN WHEAT FLOUR), WHEY,
CULTURED CREAM, NONFAT MILK,
SALT, BUTTER (PASTEURIZED CREAM,
SALT), DRIED CHEDDAR CHEESE
(CULTURED PASTEURIZED MILK, SALT,
NON-ANIMAL ENZYMES), CORN
STARCH, CITRIC ACID, ANNATTO
EXTRACT (FOR COLOR), LACTIC ACID,
SUNFLOWER LECITHIN, SILICON
DIOXIDE (FOR ANTICAKING), SODIUM
PHOSPHATE.

CONTAINS WHEAT AND MILK INGREDIENTS.

Organic Macaroni & Cheese Classic Cheddar Yummier Than Ever



MEET BERNIEL

Bernie was Annie's pet Dutch rabbit. When she started the company, Annie chose him to be our official "rabbit of approval" representing the simplicity, care and goodness in all of our products



Dear Friend,

In celebration of nearly 30 years of mac & cheese goodness, we've gone all out to make it better. In that spirit, our mac & cheese masters headed back to the kitchen on a mission for more yum. After hundreds of batches and licked bowls, we came up with a richer, more flavorful recipe. Even the noodle got an upgrade for better texture! You'll notice, however, that one thing is staying the same - our commitment to never using any GMOs. artificial flavors, synthetic colors or preservatives.

We get letters every day from parents and kids who love our honest foods. We even have a bulletin board where we post our favorites! When our team discovered a way to make our recipe even more totally delicious, we had you and your letters in mind. So make a bowl and tell us what you think!

Bue for now, All of us at Annie's

Annie's Way In 8 Minutes



EXTRA O ADD:

O BOIL: 6 cins water in a medium saucepan.

Ni cup reduced

2 Thep salled

butter to the Warm taucepon.

tal milk and



posta, bring to boil, Cook 6-8 minutes, or until done, stirring occasionally.



O DRAIN PASTA: in colunder. While pasta is draining...

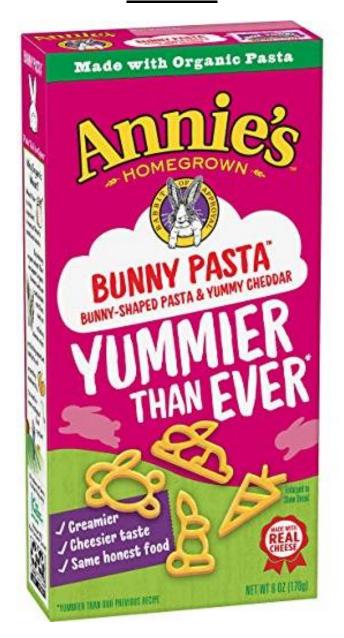


ANNIE'S SUGGESTIONS:

For an even RICHER flavor, add an additional 2 tablespoons salted butter. For a CREAMY, TANGY version, replace milk with 3 tablespoons Enjoy! of plain whole milk yogurt.

BEST INGREDIENTS: ORGANIC PASTA
(ORGANIC WHEAT FLOUR), ORGANIC
WHEY, ORGANIC CULTURED CREAM,
ORGANIC NONFAT MILK, SALT,
ORGANIC BUTTER (ORGANIC
PASTEURIZED CREAM, SALT), ORGANIC
DRIED CHEDDAR CHEESE (ORGANIC
CULTURED PASTEURIZED MILK, SALT,
NON-ANIMAL ENZYMES), ORGANIC
CORN STARCH, ORGANIC ANNATTO
EXTRACT (FOR COLOR), CITRIC ACID,
LACTIC ACID, SODIUM PHOSPHATE,
SILICON DIOXIDE (FOR ANTICAKING).
CONTAINS WHEAT AND MILK
INGREDIENTS.

Bunny Pasta Yummier Than <u>Ever</u>



made with goodness

- ✓ No Artificial Flavors, Synthetic Colors or Preservatives
- 🗸 10g Protein
- Cheese from Cows Not Treated with rBST*

BEST INGREDIENTS: ORGANIC PASTA (ORGANIC WHEAT FLOUR, ORGANIC WHOLE GRAIN WHEAT FLOUR), WHEY, CULTURED CREAM, NONFAT MILK, **SALT, BUTTER** (PASTEURIZED CREAM, SALT), DRIED CHEDDAR CHEESE (CULTURED PASTEURIZED MILK, SALT, NON-ANIMAL ENZYMES), CORN STARCH, CITRIC ACID, ANNATTO **EXTRACT** (FOR COLOR), **LACTIC ACID**, SUNFLOWER LECITHIN, SILICON **DIOXIDE** (FOR ANTICAKING), **SODIUM** PHOSPHATE.

CONTAINS WHEAT AND MILK INGREDIENTS.

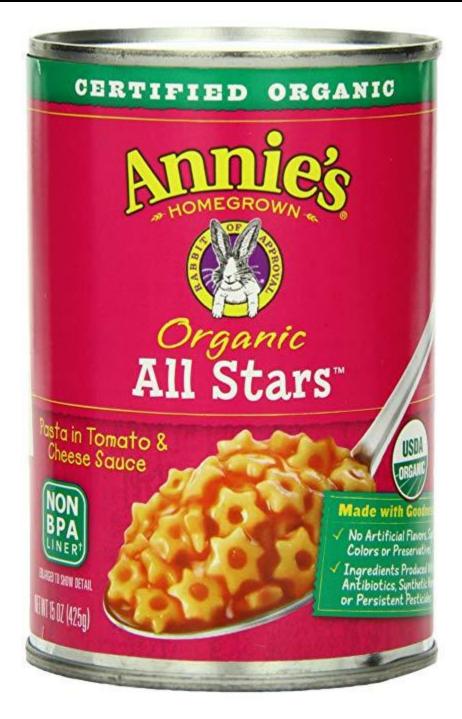
Organic Cheesy Ravioli





BEST INGREDIENTS: Water, Organic Wheat Flour, Organic Tomato Paste, Organic Brown Rice Flour, Organic Cane Sugar, Organic Cheddar Cheese (Organic Cultured Pasteurized Milk, Salt, Non-Animal Enzymes, Sodium Phosphate), Organic Rice Starch, Sea Salt, Organic Mustard Flour, Organic Corn Starch, Organic Onion Powder, Organic Garlic Powder, Citric Acid, Organic Paprika, Organic White Pepper. CONTAINS MILK AND WHEAT. Made in USA For Annie's Homegrown © 2012 ANNIE'S, INC. BERKELEY, CA 94710

Organic All Stars Pasta in Tomato & Cheese Sauce



BEST INGREDIENTS:

WATER, ORGANIC TOMATO PUREE (WATER, ORGANIC TOMATO PASTE), ORGANIC MACARONI STARS (ORGANIC SEMOLINA [WHEAT], WATER), ORGANIC EVAPORATED CANE JUICE, SEA SALT, ORGANIC CORN STARCH, ORGANIC CHEDDAR CHEESE (ORGANIC CULTURED MILK, ENZYMES, SALT), CITRIC ACID, ORGANIC ONION POWDER, ORGANIC PAPRIKA, ORGANIC GARLIC POWDER. CONTAINS WHEAT, MILK.

Organic Bernie's Farm Fruit Snacks



BEST INGREDIENTS: Tapioca
Syrup*, Cane Sugar*, Tapioca Syrup
Solids*, Pear Juice Concentrate*,
Water, Pectin, Citric Acid, Carrot
Juice Concentrate*, Sweet Potato
Juice Concentrate*, Sodium
Citrate, Ascorbic Acid (Vitamin C),
Sunflower Ull*, Natural Flavor,
Color* (black carrot*, blackcurrant*,
annatto* extracts), Lemon Juice
Concentrate*, Carnauba Wax*.
* Organic

Organic Bunny Farm Fruit Snacks Berry Patch





Organic Frosted Oat Flakes

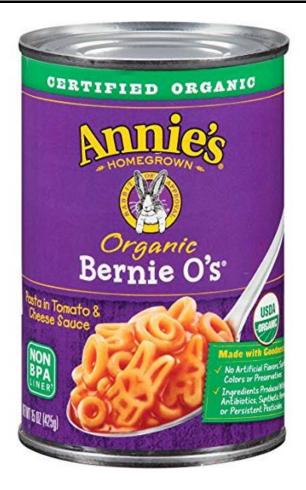




Nutrition Facts Serving Size 3/4 Cup (32g) Servings Per Container about 9 Frosted 1/2 Cup Skim Milk 0at Flakes **Amount Per Serving Calories** 130 170 Calories from Fat 10 10 % Daily Value** Total Fat 1g* Saturated Fat 0g 0% 0% Trans Fat 0g Cholesterol Omg 0% 1% Sodium 90mg 4% 6% Total Carb. 27g 9% 11% Dietary Fiber 3g 12% 12% Sugars 8g Protein 3g Vitamin A 0% 4% Vitamin C 0% 2% Calcium 0% 15% *Amount in cereal. A serving of cereal plus skim milk provides 1.5g total fat, less than 5mg cholesterol, 150mg sodium, 32g total carbohydrate (13g sugars), and 7g protein. Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs: Calories: 2.000 2.500 Total Fat Less than 65g 80g Sat Fat Less than 20g Cholesterol Less than 300mg 300mg 2,400mg Sodium Less than 2,400mg 3,500mg 3,500mg Potassium Total Carbohydrate 300g 375g Dietary Fiber

BEST INGREDIENTS: WHOLE
GRAIN OATS*, WHOLE GRAIN
WHEAT*, CANE SUGAR*,
TAPIOCA SYRUP*, SEA SALT,
SUGAR SYRUP*, VANILLA
EXTRACT*, NATURAL FLAVOR.
VITAMIN E (MIXED
TOCOPHEROLS) ADDED TO
RETAIN FRESHNESS.
*ORGANIC INGREDIENTS
CONTAINS WHEAT INGREDIENTS.
MADE ON SHARED EQUIPMENT THAT
ALSO PROCESSES SOY AND SESAME.

Organic Bernie o's Pasta in Tomato & Cheese Sauce



BEST INGREDIENTS: Water,
Organic Pasta (Organic Semolina
Wheat), Organic Tomato Paste,
Organic Cane Sugar, Sea Salt,
Organic Corn Starch, Organic
Cheddar Cheese (Organic Cultured
Pasteurized Milk, Salt, Non-Animal
Enzymes), Citric Acid, Organic
Onion Powder, Organic Paprika,
Organic Garlic Powder.
CONTAINS MILK AND WHEAT.
Made on shared equipment that also
processes egg and soy.

Exhibit B

Archived Content

The content on this page is provided for reference purposes only. This content has not been altered or updated since it was archived.

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Home Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters Inspections, Compliance, Enforcement, and Criminal Investigations

Fresh Express Incorporated 10/6/10



Department of Health and Human Services

Public Health Service Food and Drug Administration San Francisco District 1431 Harbor Bay Parkway Alameda. CA 94502-7070

Telephone: 510/337-6700

WARNING LETTER

Via UPS

October 6, 2010

Fernando Aguirre, President and CEO Chiquita Brands International, Inc. and Fresh Express, Incorporated 250 East Fifth Street Cincinnati, OR 45202

Dear Mr. Aquirre:

Starting on May 21, 2010 and ending on June 10, 2010, the Food and Drug Administration (FDA) inspected your food manufacturing facility located at 900 E. Blanco Road, Salinas, California. During this inspection, FDA investigators collected labels for your products and reviewed their labeling at

http://www.chiquita.com¹. Based on our review, we have concluded that your Chiquita brand "Pineapple Bites with Coconut" and "Pineapple Bites" products are misbranded in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and FDA regulations through links at FDA's Internet home page at http://www.fda.gov².

Specifically, your "Pineapple Bites with Coconut" product is misbranded within the meaning of Section 403(a) of the Act [21 U.S.C. § 343(a)] in that its statement of identity, "Pineapple Bites with Coconut", is false and misleading. The ingredient statement for this product states that it is made with coconut; however, our investigation determined that this product is made with a coconut flavor spray. The characterizing flavor of your Pineapple with Coconut product must be identified in accordance with 21 CFR 101.22(i)(1)(iii) (for example. "coconut flavor").

Your "Pineapple Bites" and "Pineapple Bites with Coconut" products are misbranded within the meaning of Section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because their labeling bears nutrient content claims but the products do not meet the requirements for the claims.

Specifically, their labeling includes the claim "Plus ... Antioxidants." However, this claim does not include the names of the nutrients that are the subject of the claim or, alternatively, link the term "antioxidants" by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity. 21 CFR 101.54(g)(4). Your use of this antioxidant claim therefore misbrands your products under section 403(r)(2)(A)(i) of the Act $[21 \text{ U.S.C. } \S 343(r)(2)(A)(i)]$.

Your "Pineapple Bites" and "Pineapple Bites with Coconut" products also bear the claim "Plus Phytonutrients." "Phytonutrients" are not nutrients for which a recommended daily intake (RDI) or daily recommended value (DRV) has been established. Therefore, nutrient content claims regarding "phytonutrients" are not authorized and further misbrand your products under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)]. To the extent phytonutrients are intended to be the basis for an antioxidant nutrient content claim, that use would violate FDA regulations for the same reason and because phytonutrients are not recognized as having antioxidant activity. 21 CFR 101.54(g)(1) and (2).

Both your "Pineapple Bites" and "Pineapple Bites with Coconut" products also bear the statement "Only 40 Calories." This statement implies that the products are "low calorie" foods. A "low calorie" claim may be made if a food with a reference amount customarily consumed (RACC) greater than 30 grams (g) or greater than 2 tablespoons does not provide more than 40 calories per RACC. 21 CFR 101.60(b)(2)(i)(A). The RACC established for pineapple is 140 g. See 21 CFR 101.12(b) (Table 2, Fruits and Fruit Juices, All other fruits fresh, canned, or frozen).

The nutrition information for both products states that there are 40 calories per 1 piece (80 g) of product; this equals about 70 calories per RACC. Therefore, under 21 CFR 101.13(i)(2), the products are required to carry a disclaimer adjacent to the claim, e.g., "Only 40 calories per serving, not a low calorie food". Because your products fail to bear the required disclaimer, they are misbranded within the meaning of section 403(r)(1)(A) of the Act.

The "Pineapple Bites" and "Pineapple Bites with Coconut" products are further misbranded within the meaning of section 403(k) of the Act [21 U.S.C. 343(k)] in that they contain the chemical preservatives ascorbic acid and citric acid but their labels fail to declare these preservatives with a description of their functions. 21 CFR 101.22. Further, the ingredients ascorbic acid and citric acid must be declared by their common or usual names. 21 CFR 101.4(a).

This letter is not intended to be an all-inclusive review of your firm's products and processes. It is your responsibility to ensure that your firm and your products comply with the Act and FDA, regulations. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. For instance, we may take further action to seize your product or enjoin your firm from operating.

We also note that, FDA (through its contractor) obtained two samples of Fresh Express Hearts of Romaine the testing of which yielded human pathogens. One sample was found to contain *Salmonella Anatum*; another sample was found to contain *E. coli 0157:H7*. We acknowledge that you issued letters to your customers in an effort to recall affected products. However, FDA recommends that you review your firm's criteria for receipt of raw product, your procedures for ensuring that wash, flume and processing water do not contaminate your products and any other conditions and practices that may relate to the cause of the contamination.

We further acknowledge your June 25, 2010 response to the Good Manufacturing Practices violations cited in the FDA Form 483 regarding this inspection. In your response, you committed to:

- · Retrain employees to replace or sanitize their gloves after contacting unsanitized surfaces;
- Include the dryer hoist controls and the equipment control panels that involve direct employee contact in your daily wash and sanitation procedures;
- Create a new storage system for aprons, gloves, and sleeve guards for times during manufacturing when they are not in use; and
- Modify your cutting surface inspection and replacement program so that cutting surfaces will be changed after every (b)(4) of use.

However, you did not provide documentation to demonstrate that these corrections have been made. You also did not address the observation that your technician improperly read the free chlorine indicator tests in the flume water. Please provide this information and documentation in your response to this Warning Letter.

In addition to the labeling issues identified above, we note that the available labeling space is at least 6" in height; therefore, the size of the nutrition information declared on these packages is not appropriate and does not meet the formatting requirements under 21 CFR 101.9(d), including hairline and footnote requirements. We note that since some of the nutrients are at insignificant levels, a shortened version of the Nutrition Facts panel may be used, e.g., the statement "Not a significant source of dietary fiber", at the bottom of the table of nutrient values as allowed under 21 CFR 101.9(c).

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of

the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Please include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to:

Darlene B. Almogela Director of Compliance United States Food and Drug Administration 1431 Harbor Bay Parkway Alameda, CA 94502

If you have any questions about the content of this letter please contact Sergio Chavez, Compliance Officer, at 510-337-6886.

/s/

Barbara Cassens District Director

Page Last Updated: 10/08/2010

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 Ph. 1-888-INFO-FDA (1-888-463-6332) Email FDA



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U.S. Department of Health & Human Services

Links on this page:

- 1. http://www.chiquita.com/
- 2. http://www.fda.gov

Exhibit C

Wonder Natural Foods Corp. 7/13/15



Public Health Service Food and Drug Administration College Park, MD 20740

July 13, 2015

WARNING LETTER

VIA OVERNIGHT MAIL

Mr. Stuart Lasdon, Owner Wonder Natural Foods Corp. 30 Blank Ln Watermill, NY 11976

Re: 460929

Dear Mr. Lasdon,

The Food and Drug Administration (FDA) reviewed the labels for your Better'n Peanut Butter Original (16 oz.) product in February 2015. The label for this product directs the consumer to your website at the Internet address www.betternpeanutbutter.com. We examined your website in June of 2015. Based on our review, we have concluded that this product is misbranded within the meaning of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 343] and its implementing regulations found in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and FDA regulations through links on FDA's home page at http://www.fda.gov (<a href="http://

The significant violations are as follows:

1. Your Better'n Peanut Butter Original (16 oz.) product is misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product label and labeling bear nutrient content claims, but the product does not meet the requirements to make such claims.

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation authorizing the use of such a claim. Characterizing the level of a nutrient on the food labeling of a product without complying with the specific

requirements pertaining to the nutrient content claim for that nutrient misbrands the product under section 403(r)(1) (A) of the Act. Specifically,

- a. Your website at www.betternpeanutbutter.com/index.php bears an implied nutrient content claim because it bears a statement suggesting that the product may be useful in maintaining healthy dietary practices, and that statement is made in connection with a claim or statement about a nutrient. The labeling of your Better'n Peanut Butter Original (16 oz.) product on your website bears the claim "healthy" in connection with the statement "low fat, low calorie;"; however, the product does not meet the requirements for use of a "healthy" nutrient content claim that are set forth in 21 CFR 101.65(d)(2). In accordance with 21 CFR 101.65(d)(2)(i)(F), you may use the term "healthy" as an implied nutrient content claim on the label or in the labeling of certain foods provided that the food, among other things, contains at least 10% of the RDI or the DRV per Reference Amount Customarily Consumed (RACC) for one or more of vitamin A, vitamin C, calcium, iron, protein, or fiber. According to the Nutrition Facts panel, your Better'n Peanut Butter Original (16 oz) product does not contain at least 10 percent of the RDI or the DRV per RACC for any of these nutrients. Accordingly, your product does not meet the requirements for use of a "healthy" nutrient content claim on a food label [21 CFR 101.65(d)(2)]. Your product is thus misbranded within the meaning of section 403(r)(1)(A) of the Act.
- b. Your website at www.betternpeanutbutter.com/index.php bears the nutrient content claim "low calorie;"; however, the product does not meet the requirements to bear the claim because it provides more than 40 calories per RACC and per 50g [21 CFR 101.60(b)(2)(i)
 (B)].
- c. The label bears the nutrient content claim "No Cholesterol." As required by 21 CFR 101.13(e)(2) and 21 CFR 101.62(d)(1)(i)(D), if the food contains less than 2 mg of cholesterol per RACC without the benefit of special processing, alteration, formulation or reformulation to lower cholesterol content, a claim about the lack of cholesterol in the food must disclose that cholesterol is not usually present in the food (e.g., "applesauce, a cholesterol-free food"). Peanut butter and peanut spread products do not contain cholesterol, and therefore the label of your product should disclose that cholesterol is not usually present in the food.
- 2. Your product is misbranded within the meaning of section 403(i)(1) of the Act in that "Better'n Peanut Butter" is not an appropriate statement of identity for a food [21 CFR 101.3(a)].
- 3. Your product is misbranded within the meaning of 403(i)(2) of the Act in that the ingredients are not declared in accordance with 21 CFR 101.4. Ingredients must be listed by their common or usual name in descending order of predominance by weight. Specifically:
 - a. The ingredient list declares "peanuts (as defatted peanut flour, peanut butter and natural peanut oils)." As stated above, according to the ingredient statement, this product does not appear to be made using peanuts as an ingredient. The referenced ingredient declaration is not allowed under 21 CFR 101.4(a)(1), which requires that ingredients are listed by common or usual name in descending order of predominance. Sub-ingredients of multi-component foods can be declared parenthetically under 21 CFR 101.4(b)(2). However, defatted peanut flour, peanut butter and natural peanut oils are not sub-ingredients of peanuts. The common or usual names of the ingredients actually used to make this product appear to be defatted peanut flour, peanut butter and peanut oil. Furthermore, if any of these ingredients are multi-component ingredients (e.g., peanut butter), the sub-ingredients must be declared in accordance with 21 CFR 101.4(b)(2).

- b. "Grain syrup" is not an adequate common or usual name for an ingredient,
- c. There is no provision in 21 CFR 101.4 that allows for the combined declaration of "natural colors and flavors." In fact, we note that any added color is artificially coloring a food; hence the labeling provisions under 21 CFR 101.22(k)(2).
- 4. Your product is misbranded under 403(i)(1) and 403(g)(I) of the Act because it purports to be and is represented as peanut spread and peanut butter, in the labeling. The website at www.betternpeanutbutter.com/nutrition.php characterizes the product as "an all-natural, delicious peanut butter spread," and "diet peanut butter." The product does not meet the description for peanut spread or the requirements in the standard of identity for peanut butter. Peanut spread must meet certain requirements for protein content as described in 21 CFR 102.23(b)(1)(i) or (ii). Section 102.23(b)(1)(i) requires protein content of at least 24 percent by weight (if the overall biological quality of the protein contained in the product is at least 68 percent that of casein). For a 32 gram serving, the protein content would be between 7 to 8 grams. Better'n Peanut Butter lists 4 grams of protein per 32 gram serving. Section 102.23(b)(I)(ii) requires a minimum of 16.6 percent by weight of protein (if the overall biological quality of the protein contained in the product is equal to or greater than that of casein). For a 32 gram serving, this protein content would be 5 grams. The standard for peanut butter in 21 CFR 164.150 requires the food to contain at least 90 percent peanut ingredients, which are specified in 21 CFR 164.150(b). Defatted peanut flour, which appears to be the most predominant ingredient, is not an acceptable peanut ingredient under the standard.

The above violations are not meant to be an all-inclusive list of violations that may exist in connection with your products. It is your responsibility to ensure that your products comply with the Act and its implementing regulations. You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in FDA taking regulatory action without further notice, such as seizure and/or injunction.

In addition, we offer the following comments:

- We note that the panel to the right of the principal display panel (PDP) bears the nutrient content claim "40% fewer calories." Based on your product name, "Better'n Peanut Butter," we understand the reference food for this claim to be peanut butter. However, as discussed above, "Better'n Peanut Butter" is not an appropriate statement of identity for a food. Be advised that for a "fewer calories" claim, the identity of the reference food must appear in immediate proximity to the most prominent such claim as required by 21 CFR 101.60(b)(4)(ii)(A).
- We note that the PDP and the panel to the right of the PDP bear the nutrient content claim "85% less fat." Based
 on your product name, "Better'n Peanut Butter," we understand the reference food for this claim to be peanut
 butter. However, as discussed above, "Better'n Peanut Butter" is not an appropriate statement of identity for a
 food. Be advised that for a "less fat" claim, the identity of the reference food must appear in immediate proximity
 to the most prominent claim as required by 21 CFR 101.62(b)(4)(ii)(A).
- We note that your website makes the claim "no refined sugars." The intent of your claim may not be clear to
 consumers and may mislead those who are seeking products that are sugar-free or contain no added sugar. We
 recommend that you clarify the meaning of your claim.
- The "made with real peanuts" statement is potentially misleading to consumers because it may suggest that
 peanuts are directly added to the product or that you use peanuts as starting ingredients to manufacture this
 product. Based on the ingredient declaration, it appears that this is not the case. It appears that you are starting
 with processed ingredients derived from peanuts such as defatted peanut flour, peanut butter and peanut oil.
 Therefore, we suggest that the statement be clarified.
- We note that the label bears the claim "No Preservatives." We note that if any ingredients such as tocopherol or sodium ascorbate are being used as preservatives, this statement would be false and cause the product to be misbranded under 403(a)(l).



- We note that the nutrition information is provided in a linear format. As specified in 21 CFR 101.9(j)(13)(ii), nutrition information may be provided in a tabular or linear (i.e., string) format rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the label will not accommodate a tabular display.
- The label uses the term "dehydrated cane juice" in the ingredient list. FDA is in the process of developing guidance on the common or usual name of this ingredient. We published a draft guidance for comment in October 2009

(<u>http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm181491.htm</u>

(http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm181491.htm)), and on March 5, 2014, we reopened the comment period for this draft guidance until May 5, 2014. We intend to issue final guidance after reviewing the comments received. We recommend that you check the FDA website (www.fda.gov) regularly or sign up for email updates to keep up with the latest regulatory developments, including the issuance of that final guidance. You can subscribe to email updates from FDA's Center for Food Safety and Applied Nutrition (CFSAN) at https://public.govdelivery.com/accounts? USFDA/subscriber/new?topic_id=USFDA_26 (https://public.govdelivery.com/accounts?

- The information panel contains intervening material in the ingredients list such as the words "pure" and "natural" preceding the words "water" and "peanut oils."
- The street address must be included as part of the place of business unless it is shown in a current city directory or telephone directory [21 CFR 101.5(d)].
- We note that the nutrition and ingredient information provided on the website (www.betternpeanutbutter.com/nutrition.php) for "Regular Creamy" differs from the information provided on your "Original" label. For example, on the website, the calories from fat are declared as 18 and the ingredient list includes rice syrup, soy flour, tapioca starch, paprika & annatto, and vitamins E & C (antioxidants). Alternatively, on your product label, the calories from fat is declared as 20 and the ingredient list includes peanut oil, grain syrup, natural colors, tocopherol (vitamin E) and sodium ascorbate (vitamin C). If this is the same product, we recommend that you revise any errors that appear on the label or labeling so that the information is consistent and accurate.
- The nutrition information on the website is missing declarations of trans fat, polyunsaturated fatty acids, monounsaturated fatty acids, and cholesterol amounts [21 CFR 101.9(c)(2) and (3)]. Dietary fiber is not declared in the appropriate order or indented [21 CFR 101.9(c)].

You should respond in writing within 15 working days from receipt of this letter. Your response should outline the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent their recurrence. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the corrections.

You should direct your written reply to Anam Drumheller, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions regarding this letter, you may contact Ms. Drumheller via email at anam.drumheller@fda.hhs.gov (mailto:anam.drumheller@fda.hhs.gov).

Sincerely,
/S/
William A. Correll, Jr.
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: FDA New York District

Close Out Letter

<u>Wonder Natural Foods Corp. - Close Out Letter 11/10/15</u>
 <u>(/ICECI/EnforcementActions/WarningLetters/2015/ucm475229.htm)</u>

More in 2015

(/ICECI/EnforcementActions/WarningLetters/2015/default.htm)